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EPA'S RISK ASSESSMENT PROCESS for TOLERANCE REASSESSMENT

INTRODUCTION

The Office of Pesticide Programs (OPP) evaluates the safety of pesticides to humans through a process that is known as a human health risk assessment. This process involves assessing the toxicity or hazard potential of a chemical and determining how much exposure is likely to occur to ensure that when a pesticide is used, humans are adequately protected. The process described in this paper focuses on the risk assessment process underlying tolerance reassessment, which follows the same principles as the process used to assess proposed new tolerances. Although ecological and occupational risk are analyzed for both new and existing pesticides, this paper only describes the human health risk assessment process for food, drinking water, and indoor/outdoor residential exposures.

FOOD QUALITY PROTECTION ACT TIGHTENS PESTICIDE REGULATORY STANDARDS

In setting tolerances under the Food Quality Protection Act of 1996, EPA is now considering:

- A new safety standard -- "reasonable certainty of no harm" (previously was "no unreasonable risk of adverse effects")
- Exposure from all routes -- oral (e.g., from food and drinking water), dermal (from the use of household pesticides), and inhalation (from the use of household pesticides)
- The cumulative effects of exposure to the pesticide and other substances with "common mechanisms of toxicity." When two or more substances have a "common mechanism of toxicity" it means that they affect the body in a similar manner.
- The special sensitivity of children to pesticides. EPA must include an extra safety factor in addition to the traditional 10- to 100-fold safety factor unless, on the basis of reliable data, a different level is determined to be safe for children.

Under FQPA, EPA must reassess all tolerances established before August 3, 1996 within 10 years. In doing so, EPA must give those pesticides that appear to pose the greatest risk the highest priority.

EPA also is developing a screening and testing program for chemicals with the potential to disrupt endocrine (hormone) function.

Although the process can be described in a step-by-step fashion, it often is not conducted sequentially. In fact, there are many opportunities to resolve issues and refine the assessment by obtaining better information about exposure (e.g., use and usage information) or performing more sophisticated analyses (e.g., Monte Carlo).

Managing the Process

Within OPP, the Special Review and Reregistration Division (SRRD) manages the reregistration and tolerance reassessment process for most conventional chemical pesticides. As part of implementing the 1988 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), OPP required and received the basic toxicity and residue chemistry data for pesticides registered before November 1984 (the date when 40 CFR Part 158 became effective). After that date, these data were also routinely

required before registration for any new pesticide chemical used on food crops. SRRD starts the risk assessment process by submitting all these studies and any other relevant information to the Health Effects Division (HED) for an evaluation of human health risks and to the Environmental Fate and Effects Division (EFED) for an evaluation of drinking water exposure (as well as environmental effects). Throughout the process, SRRD is responsible for requesting, receiving, and putting into review information necessary for reassessing food safety.

Developing Science Policies Related to Risk Assessment

EPA has been working with the Tolerance Reassessment Advisory Committee (TRAC) to develop or refine policies on science issues that affect risk assessment. These issues are described fully in papers prepared for the TRAC, for example, Staff Paper 20, prepared for the July 27-28 TRAC meeting, which is being updated for the September TRAC meeting. This paper includes references to certain of those issues, to indicate where policies may change or be clarified in the future based on the planned process of public notice and comment.

DATA FOR RISK ASSESSMENT

To perform a risk assessment, OPP needs data. Generally, pesticide manufacturers (i.e., registrants) are required to submit a full and comprehensive battery of toxicity, residue chemistry, and other data for food use chemicals. (These standard data are required by regulation at 40 CFR Part 158.) The toxicity data are used to identify the hazard potential of a pesticide. Residue chemistry data are used to determine the identity and amounts of pesticide residues in and on all foods and food products, including milk and meats. All the submitted data are reviewed by Agency scientists for conformity with standard practices within the discipline and Agency Test Guidelines.

In addition to these toxicity and residue chemistry data, OPP may also use other data when it is necessary to refine and make more realistic exposure assessments for residues on food. As with the base toxicity and residue chemistry data, OPP reviews these data to assure their reliability and accuracy before they are used to refine the exposure assessments. For example:

- ✔ Residue measurements from the U.S. Department of Agriculture, the Food and Drug Administration, and state monitoring programs
- ✔ Market basket or grocery store surveys conducted by registrants or users
- ✔ Information on the actual percentage of a crop treated, or
- ✔ Field-level information about how a pesticide is actually used, including actual application rates, and timing and frequency of application.

The scientific literature also contains a great deal of information related to pesticides, some of which is relevant to pesticide regulation. While data from the scientific literature do not always meet EPA's strict standards (known as Good Laboratory Practices) some do and are directly used for regulatory purposes when appropriate, or are used to indicate the need for additional data when they suggest a potential concern with a pesticide or as additional supporting evidence for a decision that is based primarily on data meeting Agency standards.

The process of improving available data is discussed in Science Policy Area 4, Dietary Exposure Estimates in the TRAC paper, Framework for Refining FQPA Science Policies.

CONDUCTING THE RISK ASSESSMENT

HED evaluates the toxicity data, the residue chemistry data, information on use, exposure measurements, and percent crop treated to establish endpoints (or effects) of concern, and to characterize food and residential exposure. These analyses, along with the drinking water exposure evaluation are the basic elements of a human health risk assessment.

> The effects identified in the hazard identification portion of a risk assessment are referred to as *toxicological endpoints*. Effects appearing quickly are known as *acute*, and longer term effects are called *chronic*.

Risk assessment follows a four-step process: (1) Hazard Identification; (2) Dose-Response Assessment; (3) Exposure Assessment; and (4) Risk Characterization.

Hazard Identification

Toxicity tests are conducted on animals, which are exposed to the test chemical by different routes: oral, dermal, and/or inhalation. The toxicity tests are designed to explore a wide spectrum of effects that may occur (e.g., birth defects, cancer, changes in fertility or ability to reproduce, neurotoxicity, harmful effects to the kidney or liver, etc.) and determine if the pesticide is causing such effects. Other sources of toxicity data include the open literature, epidemiology information, and voluntary submissions by the registrants.

Unless indicated otherwise, OPP assumes that test results in animals are relevant to the identification of hazards in humans. During hazard identification, all available toxicology data are reviewed to see what harm the pesticide might cause. Some effects may appear quickly (e.g., unsteady gait). Other effects generally appear only after years of exposure (e.g, liver damage). Knowing whether the effects are acute, chronic, or both is important in dietary exposure assessment.

Dose-Response Assessment

In evaluating a toxicity test, the HED science review team determines at what dose level the effects occurred and what population group, if any, is most sensitive to these effects. The science team also looks for the effect that occurs at the lowest dose. In some cases, there will be no response in the animals until a certain dose level is reached. This type of effect – no harmful response until a certain dose level is reached – is called a threshold effect (for example, weight loss). An effect that operates so there is some response (however small) at every dose level is called a non-threshold effect. The classic example of a non-threshold effect is certain types of cancer. The distinction between threshold and non-threshold effects is important in the application of the extra 10-fold safety factor provision of FQPA because, according to the statute, this provision only applies to threshold effects.

A threshold effect is evaluated by looking at all the doses given to the animals in a specific study and across the entire toxicology database for that chemical and identifying the highest one where no harmful effect was seen.

This level is called the No-Observed-Adverse-Effect-Level (NOAEL).

Non-threshold effects are evaluated differently. All the doses and their corresponding effects are fed into a computer model that calculates a statistical number called a q_1*. The q_1* indicates the relative potency of the chemical as a carcinogen – the higher the number, the more potent the chemical.

Peer Review Checks Results

When an HED science review team has completed its primary assessment of endpoints or effects of concern, an internal peer review committee known as the Hazard Identification Assessment Review Committee evaluates the science review team's work to ensure that all reviews are consistent with Office procedures. The committee also quantifies the dose-response relationship. See Science Policy #9, Selection of Appropriate Toxicity Endpoints (or critical effects) for Risk Assessments of Organophosphates."

Depending on the type of effects associated with a pesticide and the outcome of the peer review done by the Hazard Identification Assessment Review Committee, other internal Science Assessment Review Committees (SARCs) also may evaluate the science review team's work for specific issues. These committees include the Cancer Assessment Review Committee, the Reproductive and Developmental Toxicity Assessment Review Committee, and the Mechanism of Toxicity Assessment Review Committee.

Setting the Reference Dose

For threshold effects, dose-response is quantified by a reference dose (RfD). A chronic reference dose is an estimate of the level of exposure to a pesticide residue that is believed to have no significant harmful effects if consumed daily over a 70-year life span. An acute reference dose is an estimate of the pesticide residue to which one could be exposed in a single day without harmful acute effects. The process of putting a number on (i.e., quantifying) the toxicity portion of risk is called dose-response assessment.

The pesticide program calculates a reference dose by dividing the no-observed-adverse-effect level from an animal study by at least two uncertainty factors – a 10-fold factor to account for uncertainty in extrapolating from animals to humans (i.e., interspecies) and a 10-fold factor to account for the variation within the human population (i.e., intraspecies). In addition to these two 10-fold uncertainty factors, there is also the FQPA safety factor to address special sensitivities of infants and children and uncertainties about the toxicity and exposure dose. The proposal to retain, reduce, or remove the FQPA safety factor occurs at a later stage in the risk assessment process. It is not part of the reference dose.

<u>Exposure Assessment</u>

Pesticide exposure can occur through three routes of exposure – oral, dermal, and inhalation -- depending on where the person is and what the person is doing. EPA has interpreted the FQPA provision on aggregate exposure to mean that in addition to the pesticide exposure that occurs through food, OPP also must include exposure that occurs from other non-occupational sources, which include drinking water and residential exposure. HED evaluates exposure through food and in residential activities; EFED evaluates the drinking water exposure level. HED aggregates or combines exposures from all these sources.

Exposure through Food

As with toxicity data, an HED science review team evaluates a battery of exposure data to estimate the amount of pesticide residue that may be in foods. The actual pesticide residue measurements are done using raw agricultural commodities (i.e., grains, fruits and vegetables that are grown in the fields). To estimate the amount of pesticide residue that would be found in other food forms such as apple juice and raisins, OPP may gather additional data or perform calculations, using its knowledge based on data on how pesticide levels change during processing, etc.

It is important to note the nature of actual crop field trials, the studies conducted to determine the legal maximum amount of pesticide (the "tolerance") that may remain in or on food. These studies are conducted with the pesticide applied at the highest rate allowed and with the shortest pre-harvest interval, according to the label instructions. When the crop is harvested, sampling is done at the 'farm gate,' which means that sampling occurs before the crop has gone through any sort of processing such as washing or has entered the channels-of-trade. This will represent the highest level of pesticide that might occur on that fruit or vegetable from legal use.

What pesticide residues are present?
Metabolism studies in plants and animals show whether the pesticide or any breakdown products are present.

How much residue is present?
Crop field trials (pesticide applied at maximum label rate and crop harvested at minimum pre-harvest interval) show what the highest likely residue is.

Developing More Realistic Exposure Assessments

In reality, consumers generally are not exposed to pesticide residues in food at the tolerance levels. So, in refining or developing more realistic dietary exposure assessments, OPP often uses (as appropriate) pesticide residue measurements that were taken from foods sampled under more 'real-life' situations, such as at the grocery store or through FDA or USDA monitoring. OPP also may use information on typical use rates to compare both typical and maximum exposure. For example, information on typical use rates may come from registrants, growers, or other appropriate sources. This use rate information must be coupled with data on residues that can be expected at the various rates, such as from bridging studies (see box), since OPP cannot assume that residues are present in direct, linear proportion to the amount of pesticide applied. If studies have been done to document the effects of food processing on residues, this information also can be used. Procedures are being developed and tested on applying data from studies such as these to risk assessments.

A final piece of information that can be used in assessing dietary exposure and risk is the percentage of a given crop that is actually treated with the pesticide. HED obtains national estimates of percent crop treated from the Biological and Economic Analysis Division and also can consider regional variations where needed. The typical use of this information is shown in the table, Tiered Approach to Exposure Assessment. Without percent crop treated data, OPP will assume that 100 percent of the crop gets treated. Such an assumption can lead to an overestimate of the actual exposure level, especially for chronic exposure estimates.

EPA is considering how to handle situations where no residues are detected. In some cases, there actually is no residue present. In others, there is a residue, but it is present at levels too low for current analytical instruments or methods to detect. This is referred to as being below the level of detection. A related possibility is that the residue can be detected but is lower than the lowest level that can be accurately measured, called the limit of quantitation. EPA is developing policy on how such residues will be treated in the risk assessment. See Science Policy #3, Exposure Assessment–Interpreting "No Residues Detected."

Agricultural Use/Usage Data Help in Refining Risk Estimates

In addition to actual grower use (what pesticide is used and how, e.g. foliar application) and usage (how much, e.g., pounds per acre) practices or shipping/storage practices, data from special trials or studies are needed to form mathematical relationships to allow the information to be used in risk assessments.

Bridging Studies allow estimation of residues that might result from pesticide applications at less than the maximum label rate.

Residue Decline Studies show the relationship between pre-harvest interval and pesticide residues (i.e., at what rate do the residues naturally decline before the commodity is harvested).

Residue Degradation Studies account for reduction in pesticide residues while products are stored before consumption (e.g., potatoes and apples) or in cases where produce is harvested before maturity (e.g., bananas, tomatoes).

Processing Studies show the effects of industry and consumer cooking practices on residues; processing can alter the identity of residues and reduce or concentrate residues.

A Tiered Approach Allows Risk Assessment Refinements Where Needed

All this information is put to use in exposure assessment through a tiered approach. At the first level or tier, OPP assumes that residues are present at the level of the tolerance and that 100% of the crop is treated. These assumptions result in the highest potential level of exposure. If the risk is unacceptable at that level, more refined data are used where available. The tiered approach is used to conserve resources, since in many cases there is no need to go to higher levels of refinement. The following table shows the assumptions for the four tiers for both acute and chronic exposure estimates.

Exposure through Residential Activities

Reliable residential and other non-occupational exposure estimates are needed to aggregate exposure. However, EPA has not routinely required specific data actually measuring these exposures. HED is using available data, including:

- data generated for handler and post-application exposures;
- data from generic databases, such as the Pesticide Handlers Exposure Database, which relies on actual measured residue values; and
- results derived from models and data included in EPA's Standard Operating Procedures (SOPs) for Residential Exposure Assessment.

The SOPs include 14 categories of exposure (e.g., residential lawns, crack and crevice and broadcast treatment) and 42 scenarios within the categories. These SOPs were presented to the SAP in 1997 and published in draft the same year.

Tiered Approach for Exposure Assessment

	Acute Exposure	Chronic Exposure	Result
Tier 1	▸ Tolerance-level residues ▸ Assume 100% crop treated	▸ Tolerance-level residues ▸ Assume 100% crop treated	▸ Tolerance value used in risk assessment
Tier 2	▸ Tolerance-level residues (or highest residue found in a field trial) for items consumed as single-servings ▸ Average field trial residues for blended commodities (e.g., wheat) ▸ Assume 100% crop treated	▸ Tolerance-level residues ▸ Incorporate % crop treated information	▸ For acute assessment, tolerance or field trial value used in risk assessment ▸ For chronic assessment, multiply residue level by % crop treated (e.g., 20 ppm x 20%CT = 4 ppm)
Tier 3	▸ Use probabilistic techniques ▸ Use distribution of crop field trial residues for items consumed as single-servings ▸ Use average of crop field trial residues or 95th percentile from monitoring data for blended commodities ▸ Use % crop treated information (as part of probabilistic techniques) ▸ Use processing factors	▸ Use average of crop field trial residues or monitoring data for blended commodities ▸ Use % crop treated information ▸ Use processing factors ▸ Use refined livestock dietary burdens for meat, milk, poultry, and eggs residue values	▸ For acute assessments, use a distribution of residues, incorporating % crop treated data (e.g., if 20% of the crop is treated, there will be an 80% chance of choosing zero residue) ▸ For chronic assessments, multiply the field trial or monitoring residue value by the % crop treated (e.g., 8 ppm x 20% CT = 1.6 ppm)
Tier 4	▸ Market basket surveys (single-serving-sized samples) ▸ Use processing factors or other studies	▸ Special studies (market basket surveys, consumer processing studies, residue degradation studies, etc.)	▸ Allows additional refinement; produces more realistic exposure estimates.

Two categories of non-occupational exposures are not included in the scenarios but are modeled based on existing scenarios: schools/playgrounds/parks and public health sprays. For example, OPP uses the residential lawn scenario to estimate exposures in outdoor areas of schools, playgrounds, and parks. Indoor exposures in schools are estimated based on appropriate residential scenarios, such as crack and crevice treatment. Public health applications, such as mosquito abatement, are estimated based on deposition rates derived from models of aerial, ultra-low volume sprays together with residential turf scenarios and data on the breakdown rate of the pesticide.

Science Policy #6, Assessing Residential Exposure, includes discussion of use of these SOPs and the process and schedule for developing additional data.

Exposure through Drinking Water

The Agency generally begins its assessment by evaluating laboratory and field studies submitted by registrants to define where the pesticide moves in the environment after it is applied, what compounds are formed as it breaks down, and how long it and its breakdown products stay in the environment. The extent to which a particular pesticide moves down into groundwater or moves across land to contaminate surface water such as rivers, lakes, streams and reservoirs depends in large part on the physical and chemical properties of the pesticide combined with factors such as the type of soil and the amount of rainfall in the use areas.

Pesticide manufacturers are required to conduct many different kinds of tests that help us to understand whether a particular pesticide will move down easily into groundwater or move readily across land into surface water and whether it will persist. These tests include tests to determine how quickly a pesticide breaks down in water, how quickly sunlight degrades a pesticide, how quickly microbes in soil degrade a pesticide, how readily the pesticide binds to certain types of soil and whether the pesticide readily dissolves in water. Some tests are done in the laboratory and some tests are done outside, in actual fields where the pesticide is used. Data from these tests are used by EPA to predict whether a particular pesticide is likely to move into groundwater or surface water and at what concentrations.

EPA's predictions of whether a pesticide will move into groundwater or surface water are based on the tests described above, along with decades of experience EPA has accumulated in understanding what makes a pesticide more or less likely to move to groundwater or surface water and stay there at concentrations of concern. EPA uses mathematical models that have been developed based on this experience along with pesticide-specific data to estimate pesticide concentrations in groundwater and surface water under use conditions.

A pesticide can be used in many different locations, involving many different soil types and amounts of rainfall and depths to groundwater and proximity to surface water. Therefore, when EPA develops its initial estimate of potential pesticide concentrations in groundwater and surface water, EPA assumes conditions and circumstances that are more likely to result in movement. This is so that EPA can quickly see whether there is any likelihood whatsoever that pesticide concentrations in groundwater or surface water could be above levels of concern to human health. For example, for purposes of estimating surface water concentrations, EPA assumes that the soil is of a type that would result in more movement off-site, that the reservoir or pond is at the edge of the treated field, and that there is significant rainfall with a few days of application.

If EPA finds that it is possible that pesticide concentrations in surface water or groundwater may exceed levels of concern to human health (based on these initial estimates of potential levels in groundwater and surface water), then EPA attempts to refine its estimates using more pesticide-specific information on how and where the particular pesticide is used. Monitoring data representing actual measurements of the pesticide in groundwater and surface water are reviewed as well. If adequate monitoring data exist and these data confirm the estimates of levels in surface water or groundwater, EPA then uses all of the available data and information to produce an estimate of the concentration of the pesticide in drinking water for use in the aggregate human health risk assessment.

It is important to understand that monitoring data are highly variable. EPA must, therefore, exercise a substantial amount of judgment in the selection of a single value for use in the human health risk assessment. In general, EPA selects a concentration for use in the human health risk assessment that it believes a significant subpopulation of Americans may be exposed to in the water they drink.

Science Policy #5, Drinking Water Exposures, describes the current situation regarding review of new models and plans for further development.

Risk Characterization

The final step in risk assessment is characterization, which is the process of combining the hazard, dose-response, and exposure information to describe the overall magnitude of the public-health impact. OPP uses the 1996 EPA Risk Characterization Guidelines in conducting this process.

Setting Acceptable Risk Levels

Sometimes, when assessing risk, one of the goals is to identify the exposure level that represents an acceptable level of risk. This is done by comparing the expected or estimated exposure to toxicity. The level of toxicity is quantified as a lifetime dose for threshold effects or a q_1^* for non-threshold effects. If exposure is less than the toxicity, the risk is presumed to be acceptable. In some cases the number represents the likelihood that someone will experience the toxic effect. For example, a $1x10^{-6}$ cancer risk means that the person has a one in a million chance of developing a tumor from exposure to the pesticide.

Simply put, RISK = toxicity × exposure. Risk characterization quantifies and describes risk to human populations.

For threshold effects, risk can be expressed via a margin-of-exposure (MOE) or as a percent of the reference dose (% RfD). For nonthreshold effects, risk is expressed as a probability (e.g., $1x10^{-6}$). The formulas for these are:

MOE = NOAEL ÷ Aggregate Exposure

% RfD = Aggregate Exposure÷Reference Dose x 100

Probability (of Developing Cancer) = q_1^* × Aggregate Exposure

Aggregate Exposure is the combination of dietary exposure from food residues, nonoccupational exposure from indoor and outdoor residential pesticide applications, and drinking water exposure. Exposure from food is based on residues in foods and on what we know about what people in the United States eat and in what proportions. This latter information is known as food consumption data and is supplied by the U.S. Department of Agriculture. Food consumption data allows EPA to estimate dietary risks from food for the U.S. population as a whole along with 26 different population subgroups, including eight that are specific to infants and children, such as non-nursing infants. (See Science Policy #7, Aggregating Exposures from All Non-occupational Sources for further discussion of this issue.)

Until recently, OPP conducted both acute and chronic dietary risk assessments using its Dietary Risk Evaluation System (DRES) software. Acute dietary risk assessments conducted with DRES assume all crops with registered uses of a pesticide are treated and bear residues at tolerance or near level. The

resulting acute risk estimates are considered high-end estimates.

OPP has replaced DRES with the Dietary Exposure Evaluation Model (DEEM). This model has the capability to conduct both chronic and acute risk assessments, as well as both probabilistic and non-probabilistic risk assessments. It also includes more recent food consumption data (1989-91 and 94-96) than DRES used. These assessments will use the range or distribution of residue levels from field trials and percent crop treated or monitoring data to estimate exposure more accurately. (See Science Policy #2, Dietary Exposure Assessment– Whether and How to Use Monte Carlo Analyses and the 99.9 Percentile Issue.)

What is a Probabilistic Risk Assessment?
Probabilistic risk assessments are done to develop more refined risk estimates. They use statistical techniques to more accurately quantify both the full range of exposures to pesticide residues and the chance or probability of being exposed to any particular level.

EPA uses survey data from USDA and other sources regarding the amounts of various foods real people report they have eaten. These individual consumption values are then randomly combined with data from crop field trials and USDA and FDA on pesticide residue levels in the specified food (e.g., milligrams of pesticide in an apple).

Say, for example, EPA is doing a risk assessment for women of child-bearing age. There are data on food consumption for thousands of such women. For each woman's daily consumption of apples, the computer program randomly selects a measured residue value on apples for the pesticide being studied and multiplies the daily consumption by the pesticide residue value to obtain a daily pesticide exposure. (For that fraction of the commodity that is not treated, a zero value for pesticide residue is used.) This process is repeated many times to develop the probabilistic risk assessment.

Peer Review Ensures Risk Assessment Quality and Consistency

The various Science Assessment Review Committees (SARCs) provide internal peer review of the risk assessment components. For example, the Cancer Assessment Review Committee evaluates any cancer concerns, as appropriate. The Reproductive and Developmental Toxicity Assessment Committee will assure appropriate endpoints have been used to assess hazard to infants and children and women of child-bearing age. The Mechanism of Toxicity Assessment Review Committee considers whether a common mechanism of toxicity may exist with other pesticides.

Finally, the overall risk assessment for the pesticide is developed. The risk assessment presents a comprehensive picture of any risk concerns associated with uses of the pesticide. The last SARC, the Risk Assessment Review Committee, reviews all risk assessments for consistency.

FQPA Safety Factor Evaluation

To make a recommendation on the appropriate application of the FQPA safety factor, OPP has created the FQPA Safety Factor Committee, composed of both risk assessors (including toxicologists and exposure experts) from its science divisions and risk managers from the conventional chemical regulatory divisions (SRRD and Registration Division). When HED completes the risk characterization, this committee reviews all risk characterization information (food, residential, and drinking water exposure as well as toxicity endpoint

selection) and recommends retention, reduction, or removal of the FQPA safety factor in line with the approach presented to the FIFRA Scientific Advisory Panel in January 1998. The committee considers completeness of the toxicity database, type and severity of effects observed, and nature and quality of available exposure data. (See Science Policy Issue #1, Applying the FQPA 10-Fold Safety Factor.)

External Review

In the past, once a risk assessment, such as a "chapter" for a Reregistration Eligibility Decision, had been approved by HED management, it could be shared by SRRD with affected registrants in an effort to see if they had additional data or analysis that may significantly add to the quality of the assessment. It was often at this stage that registrants developed or gathered additional data or conducted Monte Carlo or other analyses of existing data if the initial risk assessment did not include them.

Based on discussions of the Tolerance Reassessment Advisory Committee, a group formed to assist EPA with developing ways to improve public consultation and transparency of decisionmaking on implementation of the Food Quality Protection Act, OPP has begun a pilot project to enhance public review and access to the preliminary risk assessments for the organophosphates. Once a preliminary risk assessment has had a 30-day review by the registrant for error-checking only, the risk assessment will be made available to the public. It will be placed in the OPP docket and a notice of availability will be published in the Federal Register. Following the public review period, all comments will be considered in any revisions to the risk assessment, as well as in the resulting risk mitigation and management process.

CONCLUSION

OPP's risk assessment process is evolving and improving as better data and improved models and other tools become available. More realistic risk assessments benefit both the pesticide registrants and the public.

This paper has not addressed cumulative risk assessment because this process is still under development. However, the basic risk assessment must be done for each individual pesticide in any case, to have data to use in more complex risk assessments. See Science Policy #8, How to Conduct a Cumulative Risk Assessment for Organophosphates or Other Pesticides with a Common Mechanism of Toxicity."